United States Environmental Protection Agency

EPA MEW/Navy/NASA All Parties Meeting Draft Agenda February 16, 2012

- Introductions
- Purpose of Meeting
- EPA Final TCE Toxicity Assessment Update
- Discussion
- Follow-Up/Next Steps

United States
Environmental Protection
Agency

EPA/MEW/Navy/NASA
All Parties Meeting

Final EPA TCE Toxicity Assessment Update

February 16, 2012

Presentation Outline

- Timeline of TCE Toxicity Assessment
- Background - Integrated Risk Information System (IRIS) process
- Final EPA Toxicity Assessment
- EPA TCE Regional Screening Levels and Site-specific MEW Cleanup Levels for Chronic Exposure
- Acute Exposure Concerns
- Consideration of TCE Interim Short-Term Removal Action Level for Non-Residential/Commercial Worker Scenario
- Discussion

Timeline of Activities related to EPA TCE Toxicity Assessment

- **1985** – EPA TCE Health Assessment Document
- **1987** – draft addendum
- **1989** – withdrawn from IRIS
- **1990s** – outreach meetings, development of "State-of-the-science" papers
- **2000** – "State-of-the-science" papers published in EHP
- **2001** – External Review Draft released for public comment and peer review
- **2002** – Peer review by SAB
- **2004**
  - EPA Symposium on New TCE Science
  - National Research Council (NRC) consultation on "Key Scientific Issues" initiated
- **2004** (continued)
  - Collaboration with DoD on pharmacokinetic modeling
- **2005** – EPA issue papers submitted to NRC (published in 2006 in EHP)
- **2006** – NRC report received
- **2009**
  - Agency review
  - Inter-Agency consultation
  - External Review Draft released for public comment and peer review
- **2010**
  - Public listening session
  - Public comment period closes
  - Peer review by SAB
- **2011**
  - SAB peer review report received
  - Interagency Science Discussion
  - **Posting to IRIS (Sept 28, 2011)**

Integrated Risk Information System - IRIS

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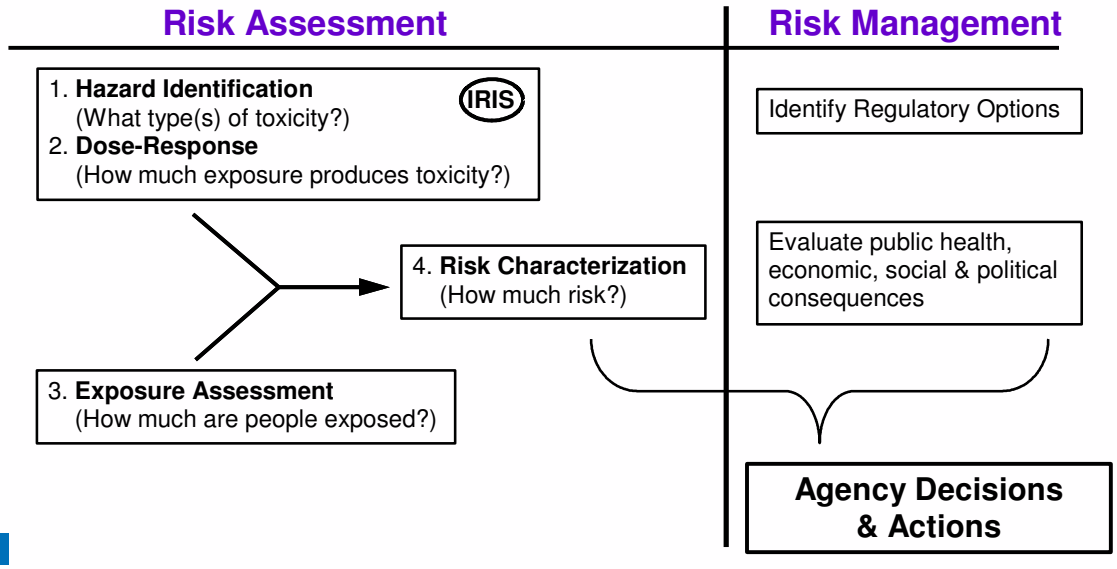
Why is IRIS Important?

Risk Assessment and Risk-Based Cleanup Levels now called EPA Regional Screening Levels (RSLs)



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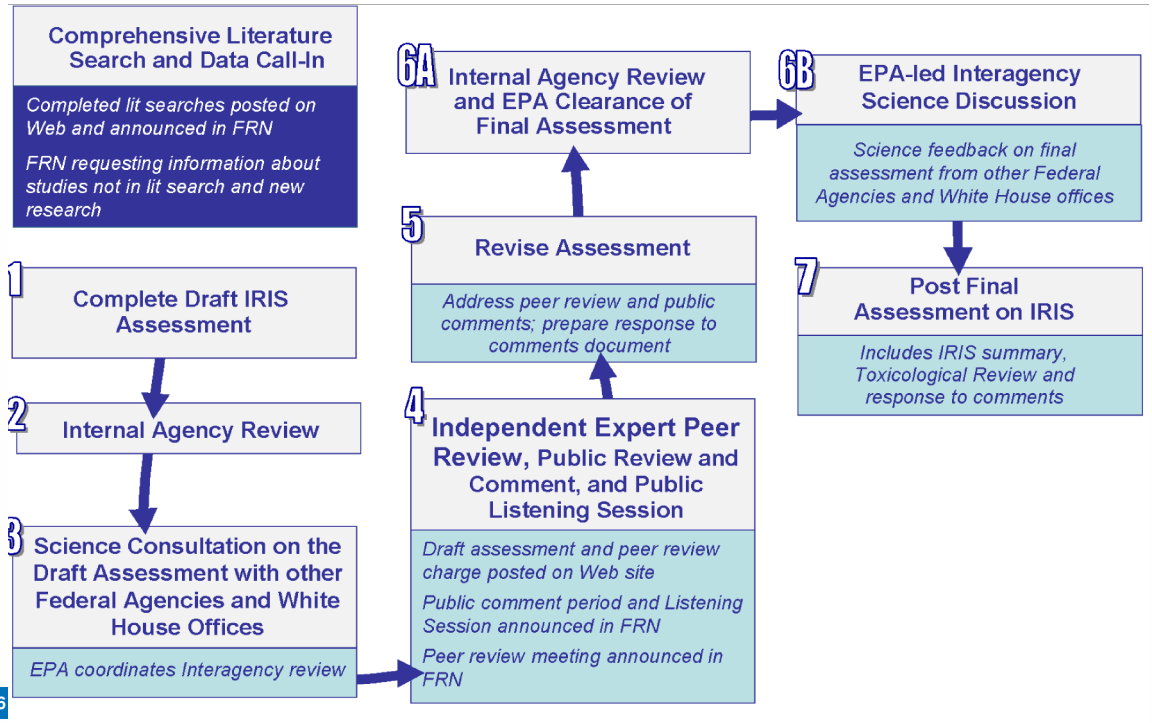
What is Involved in an IRIS Assessment?

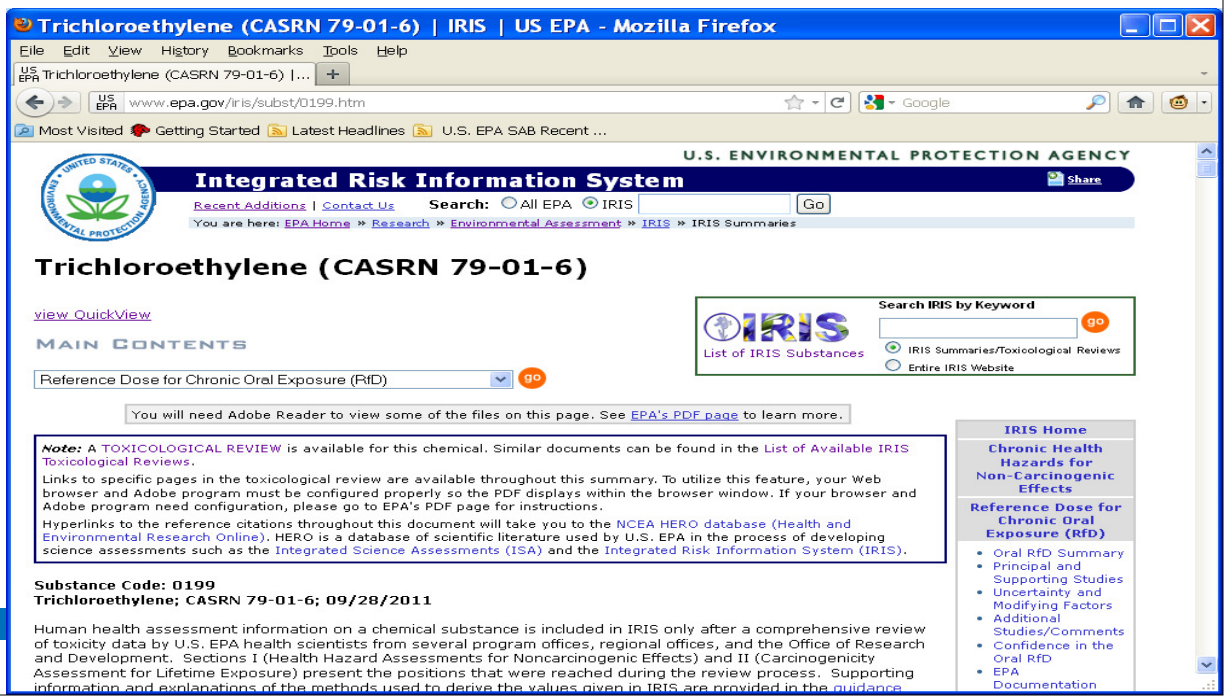
- **Review scientific literature for toxicity data**
  - identify useful (scientifically valid) studies
- **Analyze the relevant data**
  - identify critical studies, toxicities
  - quantitative modeling of dose-response
- **Write a toxicological review**
- **Calculate toxicity values for risk assessment**
  - cancer potency factors
  - non-cancer reference doses
- **Publish on IRIS database**

Current IRIS Development Process



Final EPA Toxicity Assessment

See http://www.epa.gov/iris/subst/0199.htm



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What's New in the Final TCE Toxicity Assessment

- Cancer and Non-cancer toxicity values for both oral and inhalation
- Accounts for multiple sites of cancer
- Mutagenic mode of action for kidney cancer

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TCE Hazard Assessment

Health Effects associated with TCE

- **Non-cancer**
  - Acute effects-neurological
  - Various organ systems
    - Liver
    - Kidney
  - *Immunological*
  - Reproductive
  - *Developmental*
- **Cancer**
  - *Kidney*
  - Liver
  - Lymphoma
- **Mode of Action**
  - *Mutagenic (kidney only)*
  - through metabolites

Key Features of the Final TCE Toxicity Assessment

- **Main Components of 2010 External Review Draft retained**
  - Comprehensive review of studies of TCE and TCE metabolites
  - Toxicity review organized by tissue/system
  - Multiple lines of evidence supporting major conclusions of hazard characterization and dose-response assessment
    - **Human epidemiologic data**
    - **Animal toxicity data**
    - **Mechanistic data**
    - **State-of-the-art quantitative analyses**

Key Features of the Final TCE Toxicity Assessment

- **Implemented virtually all Science Advisory Board recommendations, resulting in:**
  - **Small (< three-fold) changes in non-cancer reference dose and concentration (*RfD and RfC*)**
  - **No change to carcinogenic classification (*e.g., TCE is "carcinogenic to humans"*)**
  - **No change to cancer inhalation unit risk or oral slope factor**
  - **No change to application of Age Dependent Adjustment Factors (*ADAFs*)**

Final TCE Dose Response Assessment: Summary

- **Final Non-cancer Reference Values (RfC and RfD)**

Protective of the most sensitive effects, supported by multiple studies/endpoints:

  - **Most sensitive target organs/systems:** adult immunological system, developing fetal heart, developing immunological system
  - **Supported by kidney effects**

- **Final Cancer Risk Values**
  - **Target sites:** kidney cancer, NHL, and liver cancer
  - **Apply Age Dependent Adjustment Factors** (ADAFs) to kidney cancer risk only

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SAFETY STANDARDS FOR TCE IN AIR (MEW STUDY AREA)

Two factors that determine whether or not a health effect may occur:

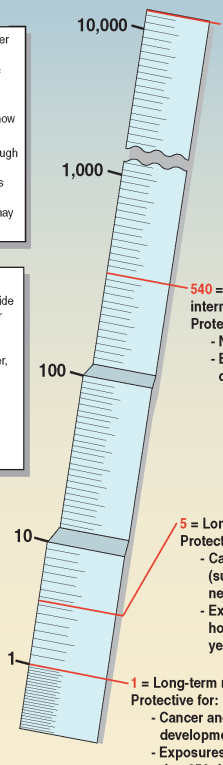
- **Level of exposure** (amount of TCE a person breathes)
- **Frequency and duration of exposure** (how often and for how long contact with TCE occurs)

If the level of exposure is low enough or short enough, no effects are expected. However, as exposures become higher and longer, the chances increase that an effect may occur.

TCE Exposure Standards

- Set at protective levels to provide a sufficient margin of safety for everyone, including "sensitive" individuals (diabetics, people taking drugs that affect the liver, infants and pregnant women)
- Because standards are developed with a margin of safety, the possibility of health effects occurring is low even if slightly above the standard

Units in micrograms per cubic meter ($\mu g/m^3$)



11,000 = ATSDR short-term standard
Protective for:
- Neurological effects
- Exposures up to 14 days

540 = ATSDR intermediate term standard
Protective for:
- Neurological effects
- Exposures lasting for 14 days up to 1 year

5 = Long-term worker standard
Protective for:
- Cancer and non-cancer effects (such as developmental, neurological, kidney)
- Exposures lasting 25 years (10 hours per day, 250 days per year, for 25 years)

1 = Long-term residential standard
Protective for:
- Cancer and non-cancer effects (such as developmental, neurological, kidney)
- Exposures lasting 30 years (24 hours per day, 350 days per year, for 30 years)

EPA Region 9

EPA TCE Regional Screening Levels and MEW Site-specific Cleanup Levels for Chronic Exposure

EPA Regional Screening Level (RSL) – December 2011				MEW Cleanup Levels
AIR (µg/m³)	Cancer (1×10^{-6})	Non-cancer		INDOOR AIR (µg/m³)
Residential (24-hr)	0.4	2		1
Commercial (8-hr)	3	9		-----
Commercial (10-hr)	2	7		5
TAP WATER				GROUNDWATER
Residential	**0.4** µg/L	3 µg/L		5 µg/L **(MCL)**

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Acute Exposure Concerns

- Developmental Endpoint
- Fetal heart formation during first trimester
- Acute Toxicity over 24 hr
- National Discussion
- Risk Communication

Consideration of TCE Interim Short-term Removal Action Level for Non-Residential/Commercial Worker Scenario

EPA comment on Air Monitoring and Soil Management Plans During Construction Activities (January 2012)

"EPA Region 9 is currently evaluating and considering a TCE interim short term removal action level of 15 micrograms per cubic meter (mg/m^3) at the MEW Site for the non-residential/commercial worker scenario. EPA's consideration of this TCE short-term removal action level is based on the new inhalation toxicity values, supporting information in the TCE Toxicity Assessment, and potential short-term exposure (10-hour worker exposure per day).

In light of this information and as a matter of good construction practice, EPA recommends that you take this interim removal action level into account and that the buildings be maximally ventilated while workers are inside the building and subsurface conduits remain open to ensure that workers are protected from Site contaminants. EPA also recommends that the Sampling Plan include monitoring for TCE in air and contingency measures if the interim removal action level is exceeded while subsurface conduits remain open and there is potential exposure to workers."

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Discussion

For more information on TCE:
http://www.epa.gov/IRIS/ and click on TCE link